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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,603	12/17/2001	James P. Snyder	EMU 2090 US	2890

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KING & SPALDING
191 PEACHTREE STREET, N.E.
ATLANTA, GA 30303-1763

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,603	SNYDER ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003 and 22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,10,16,22,26 and 31-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,10,16,22,26, 31-40,42-48, and 50-56* is/are rejected.

7)☐ Claim(s) *41,49 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Groups IV, claims 4, 10, 16, 22, 28, and 31-33, in the response filed 22 September 2003 is acknowledged. Claims 34-57, depending from the elected claims, have been added. Claims 1-3, 5-9, 11-15, 17-21, 23-27, 29, and 30 have been cancelled. Claims 4, 10, 16, 22, 26, and 31-57 are pending.

Also acknowledged is Applicant's compliance with the requirement for a species election, the compound pictured at page 17 of the response. The elected species is found to be free of the art, as discussed herein below. The search was continued to include the sub-genus, wherein Q is limited to $S(=O)_2$ and Y^1 is limited to NA^8, which has been completely searched. (The scope of all other variables is as recited in the claims.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 26, 31-33, and 50-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of treatment/prophylaxis wherein the method comprises "administering an agonistic or antagonistic effective amount of a compound of the formula." However, the claim does not recite to whom/what the compound is being

administered. One of ordinary skill would therefore be unable to determine the metes and bounds of the claims. The claims are thus rendered vague and indefinite. For Applicant's consideration, the insertion of "to a subject (patient, mammal, etc.) in need thereof" after "administering" is suggested to overcome this indefiniteness.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4, 10, 22, 34-38, 42-46, and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by HIDAKA et al (WO 99/50237). Because the reference is in Japanese, the examiner is relying in part on the corresponding US patent no. 6,403,607.

HIDAKA-WO discloses compounds consistent with formula III.2. See compounds 129-132. The compounds have utility in the treatment of peptic ulcers. See abstract. The reference further discloses pharmaceutical compositions comprising these compounds and administration of said compounds to rats. See Tables 1-6.

Claims 4, 10, 22, 32, 34, 36, 38, 42, 44, 46, 50, 52, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by HIDAKA et al (JP 4-330057). Because the reference is in Japanese, the examiner is relying in part on the Caplus abstract of the patent.

HIDAKA-JP discloses compounds consistent with formula III.2. The reference teaches that the compounds are vasodilators and antihypertensives. See abstract.

Claims 4, 10, 22, 34-36, 38, 42-44, 46, 50-52, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by LEVIN et al (WO 98/16503).

LEVIN discloses compounds consistent with formula III.2. See examples 312, 313, 324, 325, 327, 328, 329, 382, and 387. The reference further discloses pharmaceutical compositions comprising these compounds and administration of said compounds to rats. See Table I and procedure description bridging pages 147 and 148. The compounds have utility in the treatment of a number of disorders including congestive heart failure. See abstract.

Claims 4, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by BAXTER et al (J. Chem. Soc. (C), 1968).

BAXTER discloses a compound consistent with formula III.2. See compound (XII).

Claims 4 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by TATEISHI et al (US 6,399,291).

TATEISHI discloses compounds consistent with formula III.2. See compounds (7), (8), (11)-(13), (19), (23), (27), (34), (35), (37), (50), (55), (63), (71), and (76).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 10, 16, 22, 26, 33-40, 42-48, and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over HIDAKA et al (WO 99/50237) in view of FOULLON et al (US 5,994,350).

The claims are drawn to a genus of compounds defined by formula III.2 as limited by the species election, discussed above. Also claimed are pharmaceutical compositions comprising the compounds (with or without other vasopressin antagonist/agonist) and the method of treating vasopressin-related disorders comprising administering said compounds/compositions. As discussed above, the method claims are subject to an indefiniteness rejection. However, these

claims are being examined with the assumption that the methods comprise administration to a subject in need thereof.

HIDAKA-WO teaches as set forth above. The reference does not specifically exemplify the full scope of compounds as recited in the claims. The exemplified compounds have $R^6 = R^7 = R^9/R^{10} = H$, and $R^9/R^{10} = Cl$. However, the reference allows for R^a (equivalent of R^6 or R^7) to be other moieties, such as alkoxy. It also allows for R^6 or R^7 to be other moieties, such as acetamido. See page 3 (or col 2 of the US patent). Neither does the reference exemplify the treatment of humans, but the reference clearly intends such treatment. See the last four paragraphs preceding the examples.

The reference does not teach the preparation of a composition further comprising antoher VP agonist/antagonist (claim 16 and dependents) or the use thereof (claims 26 and dependents).

FOULON teaches a genus of compounds as VP antagonists. The reference further teaches that they have utility in the treatment of VP-mediated disorders such as complaints of the gastric system, including ulcers. See col 23, lines 8-26, and col 24, lines 28-47. The reference explicitly teaches administration to humans.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the exemplified compounds as taught by the reference for the art-disclosed utility as peptic ulcer treatment. For example, in the reference example cited above, replacing Cl with acetamido results in a compound consistent with the compounds recited in claims 34-40, 42-48, and 50-56. It would be further obvious to prepare pharmaceutical compositions of these compounds also for the art-disclosed utility. It would also be within the

scope of the artisan to use the compounds/compositions to treat humans with a reasonable expectation of success.

With regard to combination compositions/treatment, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine compounds of HIDAKA-WO with the VP antagonists of FOULON for the treatment of ulcers. One of ordinary skill would reasonably expect success in doing so in light of the combined teachings of the references set forth above. With regard to claims 31 and 32, after preparing the composition having compounds of HIDAKA-WO and FOULON to treat a patient with an ulcer it would be further obvious to use this remedy to treat such a patient also having hypertension or renal disease because the FOULON compounds are disclosed as having this utility.

Claims 4, 10, 22, 31-34, 36, 38, 42, 44, 46, 50, 52, and 54 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over HIDAKA et al (JP 4-330057) in view of MURUGESAN et al (US 5,939,446).

The invention is as set forth above.

HIDAKA-JP teaches as set forth above. The reference does not specifically teach the treatment of renal disease.

MURUGESAN teaches a genus of antihypertensive compounds. See col 1. The reference further teaches that these compounds, by virtue of their antihypertensive activity, have utility in the treatment of renal disorders. See col 6, lines 33-53.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the antihypertensive agents taught by HIDAKA-JP for the treatment

of renal disorders. One of ordinary skill would reasonably expect success in doing so because MURUGESAN had taught that antihypertensive agents have utility in the treatment of renal disorders.

Allowable Subject Matter

Claims 41, 49, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record teaches compounds consistent with formula III.2. However, the art does not teach or fairly suggest the particular species recited in these claims.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Leigh C. Maier
Patent Examiner
January 23, 2004